

Notice of Allowability

Application No.

10/008,524

Applicant(s)

DOORBAR, JOHN

Examiner

Mary E. Mosher, Ph.D.

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☐ This communication is responsive to 8/17/05.
2. ☒ The allowed claim(s) is/are 1-5, 7-12 and 14-64.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some* c) ☐ None of the:
- ☐ Certified copies of the priority documents have been received.
 - ☒ Certified copies of the priority documents have been received in Application No. 09/314,268.
 - ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date 5/7/04
- ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Interview Summary (PTO-413),
Paper No./Mail Date _____
- ☒ Examiner's Amendment/Comment
- ☒ Examiner's Statement of Reasons for Allowance
- ☐ Other _____

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

The application has been amended as follows:

Since the abstract filed in the amendment of 6/17/2002 was not separately indexed in the image file wrapper, a copy of the abstract is provided as a separate sheet attached to this office action so that (hopefully) there will be no question about the presence of an abstract in this application.

The Brief Description of the Drawings has been amended to include a separate description of figures 3-8 which is the same as in the patented parent case, as shown on the attached page.

REASONS FOR ALLOWANCE

The following is an examiner's statement of reasons for allowance:

The terminal disclaimer filed on 8/17/2005 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of 6,346,377 has been reviewed and is accepted. The terminal disclaimer has been recorded.

See also the reasons indicated in the office action mailed 5/18/2005.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably

accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. Mosher, Ph.D. whose telephone number is 571-272-0906. The examiner can normally be reached on M-T and alternate F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

9/15/05



MARY E. MOSHER, PH.D.
PRIMARY EXAMINER

Art Unit: 1648

Please insert the following abstract to replace the identically-worded abstract filed as part of the preliminary amendment of June 17, 2002.

ABSTRACT

The invention relates to a method of screening for precursor lesions which can lead to cervical malignancy, methods of detecting and typing human papilloma virus infections, and reagents of use in these methods.

In the specification, in the Brief Description of the Drawings on page 4&5 as amended on 6/17/2002, delete the paragraph which says:

"Figures 3-8 are micrographs showing variously stained samples as explained in the text, and"

and substitute the following paragraphs:

Figures 3(A-D) show the use of synthetic Fabs to localize HPV16 E4 protein in vivo by immunostaining of a low-grade HPV16 CIN I.

Figures 4(A-I) show the results of staining for L1, HPV16 E4, HPV63 E4, and DAPI, in low-grade HPV16-induced lesion (CIN I), high grade HPV16-induced lesion (CIN II/III), and a section through a verruca caused by HPV63.

Figures 5(A-F) show the results of staining for HPV16 E4 and biotinylated DNA probe, in low grade HPV16 lesions and in benign cutaneous warts.

Figures 6(i) (A-F) show the results of staining, for HPV16 E4, HPV1 E4, HPV63 E4, differentiation specific mucosal keratins or cutaneous keratins, and DAPI counter stain, in a HPV16-induced CIN I, an HPV-1-induced verruca, and an HPV63-induced wart.

Figures 6(ii) (A-I) show the results of staining for HPV16 E4, HPV1 E4, HPV63 E4, filaggrin, and DAPI counter stain, in a HPV16-induced CIN I, an

HPV-1-induced verruca, and an HPV63-induced wart

Figures 7(A-D) show the association of HPV16 E4 proteins with perinuclear bundles and filamentous structures in vivo.

Figures 8(A-C) show staining in the upper layers of a HPV16 CIN for an epitope in the C-terminal half of the E4 protein, the N-terminal 12 amino acids of the HPV16 E1 E4 protein, or DAPI.